

REMARKS

Applicant respectfully traverses the Examiner's rejection of the claims in view of the amendments above and the remarks below. Claims 1-18 stand rejected.

Independent claims 1 and 10 have been amended to include method steps from dependent claims 2 and 11, respectively. Dependent claims 2 and 11 have been canceled. Amended claims 1 and 10 overcome the statutory double patenting rejection in view of Applicant's other patent. Applicant has also added new claims 19 –22. Support for these amendments can be found throughout the specification, such as, for example in the FIGS., Example 1, and paragraphs 77 and 78. No new matter has been added.

Double Patenting

Claims 1 and 10 have been rejected under 35 U.S.C. 101 as claiming the same invention as that of prior U.S. Patent No. 6,413,410.

Applicant has amended claims 1 and 10. These claims no longer claim the same invention as Applicant's 6,413,410 Patent.

Claims 1-2, 5-11, and 14-18 have been rejected under the judicially created doctrine of obviousness-type double patenting in view of U.S. Patent No. 6,413,410 and/or U.S. Patent No. 6,284,125.

Independent claims 1 and 10 have been amended.

Claims Rejections - §112 1st paragraph

The pending Office Action rejects claims 3, 4, 12, and 13 pursuant to 35 U.S.C. §112 1st paragraph. In particular the Examiner states, that while the specification provides enablement for an electrochemical cell having a working and a counter electrode, the specification does not reasonably provide enablement for spacing the electrodes by a distance between about 10 microns and 500 microns *and then* during the measurement process selecting the distance between the working and counter electrode so that the reaction products from the counter electrode arrive at the working electrode. In other words, the Examiner says there is no enablement for changing the spacing between electrodes during the measurement process.

Applicant's claims do not require moving the electrodes to change the electrode spacing. As shown in Applicant's FIGS., the electrochemical cell can include multiple electrodes where different pairs of electrodes are chosen for different electrochemical testing steps. For example, one set of electrodes can be spaced apart by less than 500 microns and another set of electrodes can be spaced apart by more than 500 microns. (paragraph 77 and 78 of Applicant's specification) The choice of different electrode spacing allow multiple types of measurement to be taken, including depletion measurements and diffusion coefficient measurements. The electrodes themselves are not moved to change electrode spacing, but rather the disclosure enables the selection of different electrode pairs to provide different electrode spacing. Accordingly, claims 3, 4, 12 and 13 are fully enabled.

Claims 4 and 13

With respect to claims 4 and 13, the Examiner argues that the temporal sequence of the steps in claims would conflict if the "additional steps" were performed concurrently. Applicant respectfully disagrees.

The electrochemical cell of claims 1 and 10 can perform two (or more) types of electrochemical measurements. Claims 4 and 13 require that these methods occur concurrently. In other words, the group of steps indicated by the "additional steps" occurs within the same timeframe as the "other" steps of the claim. However, the concurrent requirement of claims 4 and 13 does not require a particular order of the individual steps within the group of "additional steps." These individual steps can conform to any required temporal sequence (apply, deplete, measure, etc.) within the claimed timeframe. Accordingly, the limitations of dependent claims 4 and 13 do not require conflicting temporal steps and Applicant respectfully requests withdrawal of the claim rejection in view of 35 U.S.C. §112, first paragraph.

Claims Rejections - §112 2nd paragraph

Claims 2-5, 11, 12, and 14 are rejected under 35 U.S.C. § 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Office Action states that,

a) Claim 1 requires the distance between the counter electrode and the working electrode to be between about 10 microns and 500 microns. Claim 2 requires “selecting a distance between the working electrode and the counter electrode so that reaction products from the counter electrode arrive at the working electrode.” It is not clear (i) whether the distance between the counter electrode and the working electrode can be changed, that is, whether the electrochemical cell has adjustable dimensions, and (ii) whether claim 2 allows from the distance between the counter electrode and the working electrode to be outside the range of between about 10 microns and about 500 microns.

The Examiner first question (i) suggests that the claims include an inherent inconsistency based on the term “selecting.” Applicant respectfully disagrees. As discussed above, Applicant’s electrochemical cell allows for the choice between different pairs of electrodes having different electrode spacing. The choice of different electrodes allows for the spacing to be *selected* without *adjusting the dimension* of the electrochemical cell. Thus, the claims are consistent and the language of claims 1 and 10 is definite.

In response to the Examiner’s second question (ii), the spacing between the counter and working electrode can be outside the range of about 10 to about 500 microns. As disclosed in the specification, the electrochemical cell can include multiple counter electrodes with different electrode spacing, and in particular, one counter electrode can be spaced less than about 500 microns from the working electrode and one counter electrode can be spaced more than about 500 microns from the working electrode. (However, it should also be noted that the language of claim 1 does not require spacing outside the range of about 10 to about 500 microns.) Applicant therefore believes the language of claims 1 and 10 is definite.

Claims 3 and 12

The Examiner states with respect to claims 3 and 12,

b) Claim 3 [12] requires the additional steps of claim 2 [11] to be conducted after the steps of claim 1 [10]. It is not clear whether this will result in two separate

measurements, not necessarily the same, indicative of the concentration of the reduced or oxidized form of the redox species;

As the specification clearly discloses, two separate measurement can occur. For example, a depletion measurement can be made prior to, during, or subsequent to the measurement of a diffusion coefficient.

Claims 5 and 14

With respect to claims 5 and 14, the Office Action inquires how many concentrations can the analyte have with respect to the phrase “a concentration of an analyte.” Applicant believes that this claim phrase, and these claims are definite. The claimed method can determine the concentration of an analyte. The claim language “a concentration of an analyte” does not appear to require that the analyte have multiple concentrations at the same point in time. Accordingly, claims 5 and 14 are definite.

Claim Rejections - §103

Claims 1, 5-8, 10, and 14-17 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,437,999 to Diebold et al. (“Diebold”). The rejection states that Diebold discloses each limitation of the rejected claims with the exception of spacing the working electrode and the counter electrode a distance between about 10 microns and 500 microns. However, the Examiner argues that Diebold teaches a 10 mil thick MYLAR™ substrate and also teaches the use of MYLAR™ to form a spacer between electrodes. Based on this use of common materials, the Examiner argues that it would have been obvious to make the spacer the same thickness as the substrate.

Applicant respectfully disagrees.

There is no suggestion that a substrate, which could have a 10 mil thickness, should be substituted for the spacer in Diebold. The substrate (4, 13) disclosed in Diebold provides a surface to build an electrode by receiving multiple layers such as conductive material (1, 12) and insulating material (3, 14) and patterning those layers. The electrodes are then combined, face to face (FIG. 5), with a spacer 43 in between, to form a finished electrochemical cell. In the

finished cell, the substrates form the outer walls.

The thickness of the substrate (i.e., the wall) has no effect on the distance between the electrodes (i.e., the thickness of the spacer). In fact, the thickness of the substrate could be varied without changing the size of the spacer. For example, the electrochemical cell could have very large walls and a very small spacer, or visa versa. As such, it is improper to suggest that the thickness of the spacer should be based on the thickness of the substrate, much less, that the spacer would have the same dimensions as the substrate.

The possible use of a common material (i.e., MYLARTM) to form the substrate and the spacer does not overcome this lack of commonality between the elements and provide the necessary motivation. The substrate has a different function in a different portion of the electrochemical cell. Simply because the spacer may be made from the *same material* as the substrate in no way suggests that the spacer should have the *same thickness* as the substrate. The use of common material to form objects of disparate size is well know. Thus, Diebold fails to teach or disclose the required electrode spacing.

Moreover, independent claims 1 and 10 require measuring a charge passed at the working electrode and obtaining the steady state current. Diebold fails to teach such method steps or to suggest that a single electrochemical cell could be capable of performing both steps. In addition, claim 10 recites applying an electric potential difference between a working electrode and a first counter electrode, as well as, applying an electric potential difference between the working electrode and a second counter electrode. Diebold completely fails to appreciate this concept. Instead, Diebold discloses measuring current at a single point in time (10 seconds) and correlating the measured current to concentration. This minimal disclosure fails to teach the claim limitation of independent claims 1 and 10.

With respect to new independent claims 21 and 22, these claims require an electrochemical cell having a porous membrane, a limitation not taught by Diebold. The porous membrane can, for example, provide a cell in which plasma is delivered substantially free of haematocrit and thus provides a more accurate electrochemical cell. Diebold completely fails to

provide any such electrochemical cell.


Applicant therefore respectfully requests withdrawal of this rejection.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. However, should any outstanding issues remain, Applicant asks that the Examiner please contact the undersigned Attorney for Applicant.

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Respectfully submitted,

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